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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,663	01/27/2005	Vladimir Knezevic	6457-66377-02	8565

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EXAMINER	
VOGEL, NANCY S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,663	KNEZEVIC ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/27/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-27 are pending in the case.

Receipt of the information disclosure statement on 1/27/05 is acknowledged.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/400,874, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The application 60/400,874 does not disclose the method of the instant claims 22-27, since there is no disclosure therein of the use of membranes formed of track-etched polymeric material, or membranes coated with an antibody or other capture molecule having an affinity to a particular target molecule.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-21 and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by Knezevic et al. (WO 02/48674).

Knezevic et al. disclose the method of making multiple substantial replicas of a biomolecular content of a sample, such as in a microarray, comprising providing a plurality of separable porous membranes in a stack for capturing biomolecules from the sample. The disclosure that the microarray may be in a multiwell sample holder (see Fig. 11 and page 31). The reference discloses that the porous membrane may be no more than 30 microns thick, comprising a core substrate which may be polycarbonate, and a coating, wherein the coating may comprise nitrocellulose (page 32-33). The reference discloses that the method may comprise analyzing the biomolecules comprising detecting the biomolecules on one or more of the separated membranes (page 13, page 38-42). The reference discloses that the stack may comprise 50 or more membranes (page 32 last line). The reference discloses that the samples in the wells may be any biomolecule (i.e proteins or nucleic acids) (page 32). The reference discloses that the membrane may be coated with a biomolecule-specific ligand, which

would be encompassed by the phrase "capture molecule having an affinity to a particular target molecule" (page 34-35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knezevic et al. (WO 02/48674) in view of Akers et al. (5,827,749) and Medical Devicelink web page, (www.devicelink.com) (article published in Nov./Dec. 2002).

Knezevic et al. is cited for the reasons set forth above.

The difference between the reference and the instant claims is that the membrane used is a track-etched membrane.

However, Akers et al. and Medical Devicelink web page disclosed track-etched membranes, and their in many laboratory applications, including filtering biological samples (see col. 9 example 4 , col. 7 lines 13-22 of Akers, see first and second paragraph of Medical Devicelink web page attached, as published in IVD Technology Nov./Dec. 2002). The reference discloses the usefulness of such membranes in filtration of samples prior to critical processes when control of the flow rate is desired, and improved resolution and accuracy is desired (page 4-5 of Medical Devicelink web page). It would have been obvious to one of ordinary skill in the art to have used a

particular type of polycarbonate filter which has controlled pore size such as those disclosed in Medical Devicelink web page and Akers et al., in the method of Knezevic et al., since all the references disclose methods of filtering biological materials through membranes, with subsequent assay of said biological materials. One would have been motivated to do so by the well known properties of such membranes, which include controlled flow rate and pore size.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,969,615. Although the conflicting claims are not identical, they are not patentably distinct from

each other because the claims of 6,969,615 disclose the method of making multiple substantial replicas of a biomolecular content of a sample, such as in a microarray, comprising providing a plurality of separable porous membranes in a stack for capturing biomolecules from the sample. The disclosure that the microarray may be in a multiwell sample holder (see Fig. 11 and column 27) would have been understood to be encompassed by the claims. The claims of 6,969,615 recite that the porous membrane may be no more than 30 microns thick, comprising a core substrate which may be polycarbonate, and a coating, wherein the coating may comprise nitrocellulose. The claims of '615 recite that the method may comprising analyzing the biomolecules comprising detecting the biomolecules on one or more of the separated membranes. The claims of '615 disclose that "pressure" may be applied to the biomolecule sample. The claims recite that the stack may comprise 50 or more membranes. The claims recite that the sample may be a tissue sample, which would contain DNA, RNA, and proteins. The claims recite that the membrane may be coated with a biomolecule-specific ligand, which be encompassed by the phrase "capture molecule having an affinity to a particular target molecule" recited in the instant claim 24.

Claims 1-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,969,615, in view of Akers et al. (5,827,749) and Medical Devicelink web page, (www.devicelink.com).

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

Knezevic et al. is cited for the reasons set forth above.

The difference between the reference and the instant claims is that the membrane used is a track-etched membrane.

However, Akers et al. and Medical Devicelink web page disclosed track-etched membranes, and their in many laboratory applications, including filtering biological samples (see col. 9 example 4 , col. 7 lines 13-22 of Akers, see first and second paragraph of Medical Devicelink web page attached, as published in IVD Technology Nov./Dec. 2002). The reference discloses the usefulness of such membranes in filtration of samples prior to critical processes when control of the flow rate is desired, and improved resolution and accuracy is desired (page 4-5 of Medical Devicelink web page). It would have been obvious to one of ordinary skill in the art to have used a particular type of polycarbonate filter which has controlled pore size such as those disclosed in Medical Devicelink web page and Akers et al., in the method of Knezevic et al., since all the references disclose methods of filtering biological materials through membranes, with subsequent assay of said biological materials. One would have been motivated to do so by the well known properties of such membranes, which include controlled flow rate and pore size.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NANCY VOGEL, PH.D.
PATENT EXAMINER